September 8, 2015

Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1631-P

Dear Mr. Slavitt:

The undersigned organizations are writing to express our concerns about provisions related to payment for biosimilar biological products in the Centers for Medicare and Medicaid Services (CMS) proposed rule for the 2016 Medicare Physician Fee Schedule.

On July 8, 2015, CMS proposed the addition of a new rule to its 2016 Medicare Physician Fee Schedule that seeks to assign one Healthcare Common Procedure Coding System (HCPCS) code to all biosimilars to a particular reference product.[1] This new rule also defines reimbursement for all biosimilars associated with a particular HCPCS code as the volume weighted average of the average sales price (ASP) of the biosimilars within a shared code.

We are encouraged by the promise of biologics and biosimilars to address diseases for which there are currently no effective therapies. The CMS proposed rule for reimbursement of biosimilars betrays that promise. This proposed reimbursement policy, which treats biosimilars as multiple source drugs, will have the effect of limiting patient and provider access based upon economic considerations, and without consideration of heterogeneity of treatment effect.

The proposed rule states that CMS is planning to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. Products that rely on a common reference product's biologics license application will be grouped into the same payment calculation. It is unclear why CMS elected to treat biosimilars as multiple source products, rather than in the manner clearly specified for biosimilars as outlined in 1847A(b)(8).

The failure of CMS to propose a reimbursement rule for biosimilars that assigns a separate and distinct HCPCS code and reimbursement rate to each biosimilar has the potential to compromise patient care, and put the sustainability of the nascent biosimilar research sector in jeopardy. Further, we are concerned that the proposed rule for payment for biosimilar biological products will create financial incentives that will drive provider prescribing, rather than quality-based incentives that encourage clinicians to provide the best care by evaluating the relative efficacy of all available biosimilar options.

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1 https://www.federalregister.gov/articles/2015/07/15/2015-16875/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

We strongly encourage the Centers for Medicare and Medicaid Services to rescind the proposed rule, and to redraft the relevant language to assign to each biosimilar a separate and distinct reimbursement rate. In addition, we request that CMS clarify that multiple biosimilars to the same reference product will not share a reimbursement rate based on pooled sales data.

If you have any questions about this letter, please contact Gretchen C. Wartman, Vice President for Policy and Program, National Minority Quality Forum, at 202-223-7563 or gwartman@nmqf.org.

Thank you.

Advocates for Responsible Care

Alamo Breast Cancer Foundation

Alliance for Patient Access (AfPA)

Crohn's and Colitis Foundation of America

Georgia State Medical Association

Health Power for Minorities, LLC

Hepatitis Foundation International

Kidney Cancer Association

Lupus and Allied Diseases Association, Inc.

National Minority Quality Forum

National Patient Advocate Foundation

National Psoriasis Foundation

New Jersey Association of Mental Health & Addiction Agencies, Inc.

Specialty Tiers Coalition of Georgia

Vietnam Veterans of America